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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,251	01/28/2004	Gerry R. Boss	26774-14267	4781

758 7590 08/18/2009

FENWICK & WEST LLP
SILICON VALLEY CENTER
801 CALIFORNIA STREET
MOUNTAIN VIEW, CA 94041

EXAMINER
YU, MELANIE J

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,251	BOSS ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *13-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1-12 and 26, in the reply filed on 10 September 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550).

Polansky teaches a method comprising:

coating an inner wall of a test tube with a capture reagent for a macromolecule of interest (par. 1009);

incubating the capture reagent with a solution containing the macromolecule under conditions to allow binding of the macromolecule to the binding partner (antigens exposed to antibodies under conditions that promote binding which indicates incubation, par. 583);

washing the capture reagent with the bound macromolecule with a wash buffer to remove unbound material while maintaining binding of the macromolecule to the binding pair (par. 579 and 583); and

eluting the macromolecule from the binding partner (par. 579 and 583).

Polansky fails to teach coating the inner wall of the test tube with a defined quantity of beads and coating the beads with a capture reagent.

Glad teaches a substrate having a capture reagent coated with a defined quantity of beads, wherein the beads are coated with a capture reagent of the macromolecules of interest (col. 3, lines 3-53), In order to provide a denser packing of particles on a substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the inner surface of the test tube of Polansky, with beads as taught by Glad, in order to provide a higher surface area for contact with a sample and allow for an increased number of attached capture reagents.

With respect to claims 2-4, Glad teaches the beads being glass (col. 3, line 48), polymer (col. 3, line 49) or agarose (col.4, lines 26-27).

With respect to claim 5, Glad teaches the binding partner attached to the beads by at least one linker molecule (NHS-activated agarose beads, col. 5, lines 4-15).

Regarding claim 11, Polansky teaches a linker molecule being protein A (par. 579).

3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550), as applied to claim 1, further in view of Orth et al. (US 2003/0153010).

Polansky in view of Glad teach a NHS linker, but do not specifically teach a linker molecule of aminopropyltriethyoxysaline.

Orth et al. teach a layered substrate comprising a layer of aminopropyltriethyoxysaline followed by a layer of NHS (par. 5), in order to bind photoactivatable biotin to the substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include on the substrate of Polansky in view of Glad, a layer of amionpropyltriethyoxysaline on the substrate under the layer of NHS as taught by Orth et al., in order to form a single self assembled monolayer on the substrate that easily binds NHS.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550), as applied to claim 1, further in view of Stimpson et al. (US 5,599,668).

Polansky in view of Glad teach a NHS linker, but do not specifically teach a linker molecule of cyanogen bromide.

Stimpson et al. teach a linker being either NHS or cyanogen bromide (col. 17, lines 37-37), in order to provide a covalent attachment

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the NHS linker of Polansky in view of Glad, with a cyanogen bromide linker as taught by Stimpson et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent linking technique and since the same expected linking effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

5. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550), as applied to claim 1, further in view of Zhang (US 2003/0046717).

Polansky in view of Glad teach a NHS linker, but do not specifically teach a linker molecule of dimethyl suberimidate.

Zhang teaches a chemical cross linker of either an NHS ester or DMS, which is dimethyl suberimidate (par. 365), in order to provide conjugation of a polypeptide.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the NHS linker of Polansky in view of Glad, with a dimethyl suberimidate linker as taught by Zhang. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent linking technique and since the same expected linking effect would have been obtained. The use of alternative and functionally equivalent

techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550), as applied to claim 1, further in view of Liu et al. (US 2004/0014101).

Polansky in view of Glad teach a NHS linker attaching a capture molecule to a bead, but fail to teach the linker molecule being an antibody.

Liu et al. teach an antibody linker (par. 43) to immobilize a nucleic acid strand on a substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the NHS linker taught by Polansky in view of Glad with an antibody linker as taught by Liu et al. because Polansky in view of Glad are generic with respect to the type of linker that may be used and one having ordinary skill would have known to use the appropriate linker based on the capture molecule to be immobilized.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550), as applied to claim 1, further in view of LaMotte (US 5,296,347).

Polansky in view of Glad teaches washing a test tube, but fail to teach removing the wash buffer by inversion of the tube.

LaMotte teaches removal of a wash buffer by inversion of a test tube (col. 19, lines 31-37) while assay components are still immobilized to the side of the test tube (col. 19, lines 4-59), in order to remove the wash buffer from the test tubes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to remove the wash buffer from the test tubes of Polansky in view of Glad, by inversion of the test tube as taught by LaMotte, in order to provide thorough and adequate removal of unbound material by washing.

8. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (US 2003/0068616) in view of Glad (US 6,156,550), as applied to claim 1, further in view of Schall et al. (US 6,699,677).

Polansky in view of Glad, as described above in the rejection of claim 1, teach the method recited in claim 26, including determining the number of capture molecules released from the receptors (spectrophotometric analysis provides the number of molecules eluted from the test tubes, par. 579), but fail to teach the binding partner being a guanine nucleotide binding protein.

Schall et al. teach an immobilized guanine nucleotide binding protein (G-protein; col. 12, lines 10-30), in order to interrogate the cell expressing the CCR1 intracellular domain.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the binding protein in the method of Polansky in view of Glad, a guanine nucleotide binding protein because Polansky in view of Glad ,describe numerous types of receptors that may be immobilized to the substrate and

one would be motivated to use the appropriate ligands for the detection of the desired analyte.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641